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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/959,125	10/28/1997	YOSHIHIKO HIGUCHI	20111-0014	4244

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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/959,125

Applicant(s)

HIGUCHI ET AL.

Examiner

Lyle A Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-5 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siddiqi (USP 4,438,067).

Siddiqi teaches a test strip with a continuous layer of polymeric hydrophilic beads and the reagents necessary to achieve the desired colorimetric reaction. Column 5 lines 21-23 teach titanium dioxide can be incorporated into the beads which has been read on the claimed "polymer beads embedding light reflective particles". Column 6 lines 10-15 teach a PVA adhesive to retain the beads, which has been read on the claimed "matrix comprising a hydrophilic high molecular weight substance". Column 5 line 14 teaches the beads have diameters of 20-200 microns, which overlaps, with a portion of the claimed particle diameters of 1-40 microns. Column 5 lines 30+ teach the beads are made of polymers derived from hydroxyacrylic acid which has been read on the claimed acrylic acid and methacrylic acid polymers.

Siddiqi is silent to the claimed content of polymer bead being 5-30 wt.% of the total reagent layer and the light reflective particle in the amount of 10-70 w/v% based upon the total content of the beads.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has predictable and well-known results. The amount of polymer beads has the well-known and expected result of controlling the amount of sample retained and the

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amount of reagent exposed to the sample (e.g. the threshold sensitivity of the test strip).

The amount of reflective particles has the well-known and expected result of reducing interference from highly color samples, such as blood. Both the amount of beads and the amount of reflective particles on the beads are result effective variables.

It would have been within the skill of the art to modify Siddiqi and select a content of polymer bead being 5-30 wt.% of the total reagent layer and the light reflective particle in the amount of 10-70 w/v% based upon the total content of the beads as optimization of a result effective variable.

Response to Arguments

Applicant's arguments with respect to claims 2-4 and 14-15 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.

Lyle A Alexander
Primary Examiner
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